

CURRICULUM VITAE

Name: Samuel David Maldonado, M.D., MPH

Date of Birth: _____

Home Address: _____

Business Address: Johnson & Johnson
Pharmaceutical Research and Development
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Education and Professional Experience:

1975 – 1982	Medical School, National Autonomous University of Honduras, Tegucigalpa, MDC. Honduras
1978 – 1980	Assistant Instructor, The Morphological Science Department, National Autonomous University of Honduras. Tegucigalpa, MDC, Honduras
1982 – 1983	Medical Social Service, Hospital Atlantida, La Ceiba, Honduras.
1983	Graduation: Medical Doctor, National Autonomous University of Honduras
1983 – 1984	Scientific Assistant, Research Division, National Autonomous University of Honduras. Tegucigalpa, MDC, Honduras
1983 – 1984	Medical Director and co-founder of Baptist Clinic Colonia Soto, Comayagua, MDC, Honduras
1985 – 1986	Delgado Community College, New Orleans, LA. Studying English
1986 – 1987	Self-study Program in preparation for ECFMG and FLEX exams. New Orleans, LA
1987 – 1988	Pediatrics Internship, Ochsner Medical Foundation, New Orleans, Louisiana
1988 – 1990	Pediatric Residency, Henry Ford Hospital, Detroit, Michigan
1990 – 1993	Regulatory Science Fellowship, US Food and Drug Administration. Rockville, MD
1990 – 1993	Clinical Fellowship in Pediatric Infectious Diseases, Children's National Medical Center and George Washington University, Washington, D. C.

Education and Professional Experience (continuation):

1992 – 1996	George Washington University, School of Public Health, Washington, D.C.
1996	Graduation: Master of Public Health. George Washington University, Washington, D.C.
1992 – 1998	Pediatrician (private contractor), Pedicall of Montgomery County. 15201 Shady Grove Road, Rockville, MD 20850
1993 – 1998	Medical Officer, Center for Drug Evaluation and Research, US FDA. Rockville, MD
1998 – 2000	Associate Director, Clinical Virology, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877
2000 – Present	Director, Pediatric Infectious Diseases, Johnson & Johnson Pharmaceutical Research and Development. [Primary responsibilities are designing and execution of pediatric clinical trials across all Johnson & Johnson pharmaceutical companies].

Medical Licenses and Certifications:

1983	Honduras Medical License	
1987	ECFMG	
1987	Louisiana State Board of Medical Examiners. Temporary License	
1988	National Board of Medical Examiners. FLEX / FIN	
1990	American Board of Pediatrics.	// Re-certified in 1997
1990	Michigan Medical License	– Inactive
1991	Maryland Medical License	
1992	District of Columbia Medical License	– Inactive
2000	Connecticut Medical License	– Inactive
2002	New Jersey State Board of Medical Examiners:	

Professional Memberships and Appointments:

1987-present	American Academy of Pediatrics
1992-present	Infectious Diseases Society of America
2000-present	American Society for Microbiology
2001-present	American Association of Pharmaceutical Physicians
2001-present	Pediatric Infectious Diseases Society
2002-present	Drug Information Association
1995-1998	Chairman, Pediatric Pharmacokinetics working group, Pediatric Subcommittee of the Medical Policy Coordinating Committee (MPCC), CDER
1996-1998	Center for Drug Evaluation and Research (CDER) Liaison to the Red Book Committee, Infectious Diseases Committee of the American Academy of Pediatrics
1998	CDER liaison to the Inter-Agency Working Group on Influenza Pandemic Preparedness and Emergency Response (GRIPPE) for the United States.

Awards and Honors:

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| 1999 | FDA Award of Merit for exceptional performance in the initiation of an immediate, national and international response to a public health emergency, the shortage of Ritonavir an important AIDS therapeutic. |
| 1998 | FDA Award of Merit for exemplary performance in the accelerated development and review of the antiretroviral drug Nelfinavir |
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CDER Team Excellence Award for: | |
| <ol style="list-style-type: none">1. Outstanding performance towards development and implementation of regulatory policies and guidances in the are of clinical pharmacology.2. Outstanding performance in the development and issuance of a comprehensive guidance for the pharmaceutical industry and FDA reviewers on "Population Pharmacokinetics." | |
| 1997 | FDA Outstanding Achievement Award: For outstanding performance as a medical reviewer and a contributor to FDA-wide initiatives |
| 1995 | On the spot cash award for outstanding job done in 1995. Division of Antiviral Drug Products, CDER, FDA |
| 1985 | Best 1985-article published in Revista Médica Hondureña (the official scientific journal of the College of Physicians of Honduras) |

Publications and Presentations:

1. **Maldonado S**, Pina LM, Figueroa M, Dagen M, Yolken R. Epidemiologic Study of Viruses of the Respiratory Tract in La Ceiba, Honduras, 1982 - 1983. *Revista Medica Hondurena*. Vol. 53 (1) 1985.
2. **Maldonado S**, Figueroa M. Epidemiologic Study of Venereal Diseases in Tegucigalpa, D.C. Honduras, 1983 - 1984. Annual Bulletin of the Research Division of the U.N.A.H., 1985.
3. **Maldonado S**, Khan W, Rodriguez W. Rapid Screening for Salmonella by Dipstick ELISA Test. Presented at:
 - a) 1991 Annual Meeting of The American Society of Microbiologist (ASM). Dallas, TX. May 5 - 9.
 - b) Fifth Annual Advances in Pediatrics Education and Scientific Forum at CNMC on May 23, 1991.
4. Khan W, **Maldonado S**, Rodriguez W. Rapid Screening for Salmonella Directly From Stools by Dipstick Enzyme-Linked Immunosorbent Assay. Presented at: 31st. Interscience Conferences on Antimicrobial Agents and Chemotherapy. Chicago, Illinois. September 30, 1991.
5. Roberts R., **Maldonado S**. FDA Center for Drug Evaluation (CDER) Pediatric Plan and New Regulations. *Drug Information Journal*, Vol. 30, No. 4. pp. 1125-1127, 1996.
6. D'Agostino Sr. R., Weintraub M., Russell H., Stepanians M., D'Agostino Jr. R., Cantilena Jr. L., Graumlich J., **Maldonado S.**, Honig P., and Anello Ch. *Clin Pharmacol Ther* 1998; 64(6):579-96
7. **Maldonado S**, Lamson M, Gigliotti M, Beebe S, Pav J, Robinson P. Pharmacokinetic (PK) Interaction Between Nevirapine (NVP) and Rifabutin (RFB). Poster presented at 39th ICAAC meeting in San Francisco, CA. September 26 - 29, 1999.
8. Sun H, Fadiran EO, Jones CD, Lesko L, Huang SM, Higgins K, Hu C, Machado S, **Maldonado S**, Williams R, Hossain M, Ette EI. Population Pharmacokinetics. A Regulatory Perspective. *Clin Pharmacokinet* 1999; 37(1):41-58
9. Chien S, Ables R, Blumer J, Chow A, Goldstein H, Kearns G, **Maldonado S**, Noel G, Wells T, Spielberg S. Single-Dose Pharmacokinetics and Tolerability of Intravenous Levofloxacin in Pediatric Patients. Presented at: 41st. Interscience Conferences on Antimicrobial Agents and Chemotherapy. Chicago, Illinois. December 16, 2001
10. Chien S, Wells TG, Bradley JS, Kearns GL, Bochinni JA, **Maldonado SD**, Noel GJ. Pharmacokinetics of Levofloxacin Oral Suspension in Children and Infants. Presented at: 42st. Interscience Conferences on Antimicrobial Agents and Chemotherapy. San Diego, California. September 27-30, 2002

Invited as Featured International Speaker at:

Grand Rounds, Department of Internal Medicine. Hospital Escuela and National Autonomous University of Honduras. Tegucigalpa, D.C.
Honduras, Central America. August 3, 1994.
Title of presentation: Drug Development, the USA Model.

Annual Meeting of the Infectious Diseases Society of Honduras,
Tegucigalpa, D.C. Honduras, Central America. August 3-4, 1994.
Title of presentations: New Developments in Anti-fungal Therapy
and New Developments in Anti-viral Therapy.

The Eighth Scientific Meeting of Instituto de Salud Publica, Santiago, Chile.
November 15 to 17, 1995. Title of Presentation: New Drug Development, the US-
FDA Model.

Grand Rounds, Hospital Regional de Juticalpa, Olanchito, Honduras. August 6,
1996. Title of presentation: Treatment of HIV infection in 1996.

VII Pan American Congress and X Brazilian Congress on Infectious Diseases.
Salvador, Bahia, Brazil. May 18 to 23, 1997. Bacterial Resistance to
Antimicrobial Agents in the USA.

Pan American Conference on Drug Regulatory Harmonization. Pan American
Health Headquarters, Washington, D. C. November 18 to 20, 1997. Invited to
lead the discussions that America's Regulators had on US-FDA cooperation and
harmonization with the other countries in the Americas. Twenty six countries,
including the United States, were represented at this meeting.

Novedades Terapéuticas: Desarrollo, Regulación, Patentamiento y
Comercialización. Buenos Aires, Argentina. April 14 and 15, 1998. Evaluation
Criteria for NDA approval by the US-FDA.

Second National Conference on Pulmonary Medicine and Thoracic Surgery.
San Pedro Sula, Honduras. September 24 and 25, 1999
Lectures on Tuberculosis and HIV-Infection, Pulmonary Manifestation of HIV
Disease, and Community Acquired Pneumonia.

Investigacion Clinica en Argentina: Nueva Oportunidad de Mercado. Buenos
Aires, Argentina. October 2-3, 2000. Lectures: "Interaccion entre la Industria
Farmaceutica y la FDA"; and "Compliance and Ethics in the Conduction of
Clinical Trials."

National Meetings:

Representing the Food and Drug Administration at the AIDS Clinical Trials Group Leadership Retreat. Presented the FDA Perspective on Issues Regarding Perinatal/Early Therapy Trials. Washington, D. C. July 17, 1995.

Representing the Food and Drug Administration at the 24th Annual Meeting of the American College of Clinical Pharmacology. Presented FDA initiatives in Pediatric Drug Development. Rockville, MD September 21, 1995.

Representing the Food and Drug Administration at the Drug Information Association (DIA) Symposium "Drug Development for Infants and Children: Rescuing the Therapeutic Orphan". Presented FDA initiatives in Pediatric Drug Development. Sheraton Washington Hotel, Washington, D. C. September 22, 1995.

Representing the Center of Drug Evaluation and Research, FDA, at the annual meeting of the Red Book Committee of the American Academy of Pediatrics. Chicago, IL., April 13 - 15, 1996.

Representing the Center of Drug Evaluation and Research, FDA, at the Clinical Development of New Drugs and Therapeutic Agents: Art, Science and New Frontiers. Sponsored by the Center for Drug Development Science (CDDS) Georgetown University and Division of Clinical Pharmacology Stanford University Medical Center. Presented: "Drug Development Based on Surrogate Endpoints and Special Populations at Stanford University, Stanford, California, July 9, 1997.

Co-Chair of the Pediatric Drug Development Workshop: Identifying the Barriers, co-sponsored by the FDA and the American Association of Pharmaceutical Scientists. Washington, D.C., May 11-13, 1998.

References: Upon Request